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PATENT/OFFICIAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

D. Clark Bennett et al.

Serial No. 08/722,659

Filed: 27 September 1996

For: USE OF HEPARINASE TO DECREASE
INFLAMMATORY RESPONSE

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: Group Art Unit: 1644
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: Examiner: A. DeCloux

REPLY BRIEF UNDER 37 C.F.R. § 1.193

Honorable Commissioner for Patents
Washington, D.C. 20231

Sir:

This is a Reply Brief in response to the Examiner's Answer issued on January 13, 2003.

This Reply Brief is being filed in triplicate. No fees are believed to be due; however, the Commissioner is also authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219 to maintain the pendency of this application.

RESPONSE

Appellants provide the following additional remarks with respect to the Examiner's Answer mailed January 13, 2003.

(11) Response to Argument

With respect to the Examiner's rejection of claims 1-7 and 18-19 under 35 U.S.C. §§102(e) or (f), Appellants respectfully provide the following remarks.

A. Inherency – Newly Raised on Appeal

The Examiner asserts for the first time on appeal that the '863 patent inherently teaches the claimed method of reducing localized inflammatory response. (See Examiner's Answer at 4,

second full paragraph.) Nowhere in the extensive prosecution of this application for the past seven years has the issue of inherency ever been raised until the Examiner's Answer. As such, Appellants object to this basis for the rejection under 35 U.S.C. §102(e) and regard this as a new ground of rejection. Appellants respectfully request that prosecution be reopened so that Appellant may have a full and fair opportunity to respond to the new ground of rejection, particularly since the Examiner has stated that the "limitation [of reducing inflammation by administration of heparinase, the very crux of the claim] would be inherent, absent evidence to the contrary." Appellants were never given the opportunity to provide evidence to rebut such a statement.

Nevertheless, the Examiner has admitted that the '863 patent does not expressly teach each and every element of the claim. The '863 patent does not teach that the local administration of heparinase reduces inflammation, but the Examiner now alleges that it would be inherent "absent evidence to the contrary." Appellants respectfully disagree.

The Federal Circuit has clearly established that the "purpose of the rule of inherency is to accommodate common knowledge, knowledge that judges might not know but that would be known to practitioners in the field." *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999). Instead, "an inherent property must necessarily be present in the invention described by the count, and it must be so recognized by persons of ordinary skill in the art." *Hitzeman v. Rutter*, 243 F.3d 1345, 1355 (Fed. Cir. 2001)(emphasis supplied). Moreover, "[i]nherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 USPQ2d 1597, 1599 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)). In fact, in reversing a district court's finding of invalidity based on anticipation by inherency under 35 U.S.C. §102(e), the Federal Circuit specifically noted that the test is determining not whether a limitation inherently results in the claimed result, but whether one skilled in the art would read the prior art as inherently disclosing the invention. *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1381 (Fed. Cir. 2002).

Appellants respectfully submit that the Examiner has failed to establish that one having ordinary skill in the art reading the '863 patent would have appreciated that administration of heparinase reduces inflammation. Instead, the Examiner attempts to negatively state that the

'863 patent disclosure is inherent because it is not "contrary to the claimed invention." What the Examiner fails to affirmatively establish, on the other hand, is that one having ordinary skill in the art would have appreciated that the delivery of heparinase as described in the '863 patent results in reduced localized inflammation arising from an ischemia/reperfusion injury in a tissue of a patient and that the amount of heparinase to be delivered to obtain this result must be "sufficient to decrease neutrophil transmigration through activated endothelium and basement membrane of said vasculature," as required by the claim. In fact, in a Declaration of Inventor under 37 CFR §1.312 of Joseph Zimmermann, the same Zimmermann of the '863 patent, Mr. Zimmermann declares, as one having ordinary skill in the art, that he himself did not appreciate that heparinase would result in a reduction of inflammation based on the disclosure in the '863 patent. (See Declaration of Inventor under 37 CFR §1.132, executed July 31, 2001, as filed with Response of August 9, 2001.) Therefore, Appellants have already established that one skilled in the art did not appreciate that administration of heparinase would result in a decrease in inflammation according to the claimed method. As such, Appellants respectfully submit that the Examiner has not met the burden to establish that each and every element of the claims are expressly or inherently described in the '863 patent.

Moreover, to the extent the Examiner relies on an inherency argument as a new basis for the instant rejection, Appellants respectfully request that the Board consider the Rule 1.132 Declarations of Israel Vlodavsky and Richard Broughton establishing that they are not inventors of the claimed invention.¹ The Examiner did not consider these Declarations persuasive because they did not establish that the remaining inventors of the present application were not listed on the referenced patent and still constituted prior art by "another." What the Examiner has failed to note, however, is that Israel Vlodavsky and Richard Broughton further averred that the '863 patent work that forms the basis of this rejection is attributable to Clark Bennett and Pamela Danagher, and hence, not to the other named inventors in the instant application. Moreover, the courts have cautioned the Patent Office that additional "disclaiming affidavits or declarations by the other authors" are not required when a single declaration provides sufficient information to establish that the work is attributable to the named inventor. *In re Katz*, 687 F.2d 450, 455

¹ The Examiner has refused to even enter the Declarations as proof although no amendments were presented with the Declarations in the After Final Response.

(CCPA 1982). Accordingly, Appellants have already established that the work in the '863 patent that forms the basis of the instant is not by "another" as alleged.

B. Appeal Exhibits Are Properly Considered

The Examiner has refused to consider Exhibit G of the Appeal Brief and the Singer and Smith review article addressed in Sections A and B of the Appeal Brief. Appellants note that Exhibit G is recent case law regarding anticipation rejections attached for the convenience of the Board. In addition, the Singer and Smith article establishes that inflammation involves the adherence of neutrophils to an activated extracellular matrix followed by the infiltration or transmigration of neutrophils into the wounded area and clearly elucidates the differences between inflammation, tissue formation, and tissue remodeling during the wound healing process. Appellants submit that this Singer and Smith review article was provided with the Response filed March 18, 2002, and should be considered as having been properly before the Examiner during prosecution of the instant application.

C. Examiner Did Not Meet The Burden Under 35 U.S.C. § 102(f)

The Examiner maintains that the rejection under 35 U.S.C. §102(f) is proper. In particular, the Examiner acknowledges that the Examiner must presume that "appellants are the proper inventors unless there is proof that another made the invention and that appellant derived the invention from the true [inventor]." (Examiner's Answer at 3.) The Examiner, however, states that "as of this date, no [objective] evidence has been presented that validates Appellant's contention that the inventive identities are not identical." (*Id.*) Appellants respectfully disagree.

Appellants submit that in order to make such a rejection under §102(f), the Examiner must show that the inventors "did not himself invent the subject matter sought to be patented." Thus, the Examiner must affirmatively establish that Israel Vlodavsky and Richard Broughton are actual inventors of the claimed subject matter² or that Elizabeth Cauchon, Dominique Fink, Brigitte Grouix, and Ariane Hsia are not inventors of the claimed subject matter. *See, e.g., Ex parte Ida*, Appeal No. 95-4754 (Bd. Pat. App. & Int. 1999)(unpublished) and *Ex parte Raikhel*, Appeal No. 94-2232 (Bd. Pat. App. & Int. 1996)(unpublished).

² Notably, appellants filed Rule 1.132 Declarations of Israel Vlodavsky and Richard Broughton to establish that they are not the inventors of the presently claimed subject matter.

Similar to that found in *Ex parte Ida* and *Ex parte Raikhel*, the Examiner has not met the burden of establishing that the named inventors did not invent the subject matter sought to be invented. Instead, the Examiner bases this rejection on an assumption that the disclosure of the '863 patent "inherently" teaches the claimed invention. Inventorship is based on each inventor's conception of the claimed invention. Conception is the definite and permanent idea of the complete and operative invention. However, "inherency" as a basis for §102(e) cannot meet the requisite burden of proof that the named inventors are not, themselves, the inventors.

"Inherency" of a claim element can only constitute conception in the mind of an inventor if one reading the prior art would readily appreciate that such element was inherent. However, the court has held that an inventor's own failure to appreciate that a claimed element was inherent "negated the definite and permanent idea of the complete and operative invention required by the patent law for conception." *Knorr v. Pearson*, 671 F.2d 1368, 1375 (CCPA 1982). Thus, similar to Joseph Zimmermann, who failed to appreciate that administration of heparinase could result in the reduction of inflammation according to the claimed method, it is apparent that one having skill in the art did not appreciate such alleged inherent limitation. (See Declaration of Inventor under 37 CFR §1.132, executed July 31, 2001, as filed with Response of August 9, 2001.)

Moreover, it is further noted that such inherent appreciation was not formed in the minds of Israel Vlodavsky and Richard Broughton. Appellants have filed Rule 1.132 Declarations of Israel Vlodavsky and Richard Broughton establishing that they are not inventors of the claimed invention. As described above, Appellants have already established that the '863 patent work that forms the basis of this rejection is attributable to Clark Bennett and Pamela Danagher, and hence, not to the other named inventors in the instant application. Appellants hereby submit that the declarations of Zimmerman, Vlodavsky, and Broughton establish that Zimmermann did not appreciate the instantly claimed invention at the time the application for the '863 patent was filed and that the basis of the instant rejection is attributable to the common inventors, Bennett and Danagher.

The Examiner has not met the burden of affirmatively established that Israel Vlodavsky and Richard Broughton are actual inventors of the claimed subject matter or that Elizabeth Cauchon, Dominique Fink, Brigitte Grouix, and Ariane Hsia are not inventors of the claimed subject matter to properly maintain the rejection under 35 U.S.C. §102(f).

For these additional reasons, Appellants respectfully submit that the outstanding rejections should be reversed, and such action is respectfully requested.

Respectfully Submitted,

A handwritten signature in cursive script, reading "Maria L. Maebius".

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